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In re the Application of

Group Art Unit: 3772

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Examiner: Brandon Jackson

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(Patent Attorney acting for himself, pro se).

FOR: Cheek Path Airway And Cheek Pouch Anchor

1 SUBSTITUTE SPECIFICATION WITH AMENDMENTS AND AMENDED ABSTRACT,
2 RESPONSIVE TO OFFICE ACTION MAILED FEB. 21, 2007

3

4 Commissioner of Patents and Trademarks

5 Washington, D.C. 20231

6

7 Sir:

8 In response to the Office Action mailed February 21, 2007, a substitute
9 specification containing formatting corrections and amendments is appended. A
10 traverse of the rejections of claims 33 - 38 made in the Office Action mailed February
11 21, 2007 is filed separately.

12 DESCRIPTION OF SUBSTITUTE SPECIFICATION.

13 The substitute specification, submitted pursuant to 37 CFR 1.125, reflects the
14 following changes:

15 1. In response to the Office Action of February 21, 2007, the formal section
16 headings are revised and reformatted to conform to 37 CFR 1.77(b). These changes
17 appear in the required formal sections headings. Changes made in the text of section
18 headings are indicated by strike-outs and underlining. These changes in the
19 formatting of formal section headings are not intended to change the meaning or

1 content of the disclosure.

2 2. Where section headings in the original specification were incorrectly
3 formatted with underlining, that underlining has been omitted in this substitute
4 specification. This is because new underlining to show removal of inappropriate
5 original underlining would not create a visible change. The removal of underlining of
6 section headings is not intended to change the meaning or content of the disclosure.

7 3. The Preliminary Amendment dated April 22, 2004 made changes to the text
8 of the original specification before publication and before examination, but these
9 changes were omitted from the subsequently published specification (Pub. No.: US
10 2005/0103331 A1, dated May 19, 2005). The Preliminary Amendment changes
11 therefore are being repeated in this substitute specification. They are indicated by
12 strike-out and underlining in the text. Applicant notes that the Preliminary Amendment
13 was made fifteen months before the Office Action mailed February 21, 2006, and thus
14 was not made in response to that Office Action.

15 4. Claims 1 through 32 are omitted from the substitute specification because
16 they are non-elected species pursuant to the election requirement in the First Office
17 Action.

18 5. Pending claims 33 - 37 are restated as originally filed. Pending claim 38 is
19 restated as added in the Preliminary Amendment dated April 22, 2004. Claim 38 is not
20 underlined as it was addressed in the Office Action of February 21, 2007.

21 6. Paragraph numbers have been added to this substitute specification in
22 conformity with the paragraph numbers inserted by the USPTO in the Pub. No.: US
23 2005/0103331 A1.

24 7. This substitute specification includes three new amendments made after the
25 Office Action mailed February 21, 2006:

26 7.A New claims 39 and 40 are added.

27 7.B. A new formal section heading and new statement "Not applicable"
28 are added at paragraph [0003] in order to conform to formal section headings
29 suggested by 37 CFR 1.77(b). The new section heading and the "not applicable"
30 statement added at paragraph [0003] are indicated by underlining. To accommodate
31 this insertion, Paragraphs [0007] and [0008] of the published specification (Pub. No.:
32 US 2005/0103331 A1, dated May 19, 2005) were reformatted into a single paragraph

[0008] in this substitute specification, but with no substantive change in the text of paragraphs [0007] and [0008]. This reformatting enabled continuity for paragraph numbers greater than [0008] between the paragraph numbers in Pub. No.: US 2005/0103331 A1 and this substitute specification. Only paragraph numbers [0003] through [0008] in this substitute specification designate different text than do the same the paragraph numbers assigned in Pub. No.: US 2005/0103331 A1.

As indicated by strike-outs and underlining, various section headings are revised to the literal titles suggested in 37 CFR 1.77(b).

7.C. Paragraph [219] of the substitute specification has been amended to add the following sentence:

The filament could be formed of metal or a combination of metal and plastic.

Claim 34 in the original patent application recites that the spring element could be formed of at least one of metal or plastic. This amendment is made to state the use of metal within the specification as well as in the original claim. Since the use of metal to form the spring element appeared in original claim 34, no new matter is added by this amendment.

8. No new matter is added by any amendment.

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TITLE OF INVENTION:

Related Applications: CROSS REFERENCE TO RELATED APPLICATIONS.

~~Statement Regarding Federally Sponsored Research or Development:~~

[0002] No federally-sponsored research and development is involved.

[0003] Not applicable.

[0004] 1. Field of the Invention.

[0006] 2. ~~Description of Related Art:~~ Background Art.

[0008] Some persons at times breathe nasally during sleep, with the lips and jaws closed, thereby eliminating the mouth as an effective airway. Closed-mouth, nasal breathing through restricted nasal air ways reduces ventilation volume and can impair breathing and sleep. Restrictions in the nasal airway path may significantly contribute to breathing insufficiency during sleep in some persons who breathe nasally with lips closed. Scientific and medical experts have reported (or hypothesized) a variety of contributing and causal factors other than nasal airway restriction for hypopnea and apnea, such as sagging of the base of the tongue, and possibly the lower jaw, towards the throat, resulting in restriction or blockage of the throat air way. Nasal restrictions may contribute to snoring and to sleep apnea.

[0010] A variety of devices has been developed and patented by others to mechanically control a user's jaw and tongue positions to minimize sagging of tongue and mandible towards the user's throat airway. Some include oral airways. Others

are designed to function during closed-mouth, nasal breathing.

[0011] It is an objective of the instant cheek airway invention that it be capable of placement and use in combination with a wide variety of exiting jaw- and tongue-control devices, though perhaps with some modification of such devices.

[0012] Tongue-control Devices.

[0013] A non-exhaustive list of examples of tongue-control devices that incorporate airways or employ positive or negative air pressure is:

[0014] Alvarez, et al., U.S. Patent No. 5,465,734 (1995); Hart, U.S. Patent No. 5,957,133 (1999); Karell, U.S. Pat. No. 6,408,851 B1, discloses a tongue-fastening device having airway 40 and two or more internal airway openings 42 which, as depicted in Karell's figures 3 and 5, pass between the teeth. Kulick, Pub. No.: US 2002/0139375 A1 holds the tongue forward by suction, uses bite blocks 2 to prevent biting the tongue and support air passages 4 into the oral cavity. Nelson, U.S. Pat. 6,244,865 B1, discloses a tongue positioning device which includes a hollow passageway 20 in the mouthpiece for flow of breathing gasses into the mouth.

[0015] Mouthpieces and Lip-Passing Tubes.

[0016] There exists an enormous variety of mouthpieces and other devices for delivery of gasses past the user's lips into the user's mouth. Examples include snorkels and SCUBA (Self-Contained Underwater Breathing Apparatus) mouthpieces, as well as tubes, cannulae and ventilators used in medicine, surgery, anaesthesia, orthodontics, and sports. There also are numerous devices designed to ameliorate some aspect of nasal congestion, snoring, hypopnea and apnea. Some airway devices simply provide conduits to external air at ambient pressure, whereas others are designed to deliver gasses at modified pressures. Examples of the latter are CPAP (Continuous Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) machines.

[0017] Many existing oral airways pass between a user's maxillary and mandibular teeth, requiring bite blocks or other devices to prevent crushing of the airway between the teeth and thus restricting the user's jaw motion.

[0018] Devices Using Portions of the Cheek Pathway.

[0019] Nelson, in a series of U.S. Patents No. 4,170,230, (1979), 4,261,354 (1981), 4,262,666 (1981) and 4,289,127 (1981), discloses several different versions of hollow

1 tubes which traverse portions of a user's cheek pathway. Nelson's devices are
2 designed for stand-alone cheek-side positioning; that is, they are not anchored to
3 teeth-engaging or palate-engaging dental devices. Nelson does not disclose any
4 structure curving around a user's rear-tooth corner, or passing into or through a user's
5 rear-jaw gap, or extending from the user's rear-jaw gap over the user's tongue into
6 airspace in a user's rear-mouth cavity. Nelson describes and depicts his curved tube
7 as open-ended, with at least one opening internal to the user's mouth, and having a
8 length to insure that there will be an air flow opening approximate the molars at the
9 rear of the user's mouth. See, for example, Nelson, U.S. Patent 4,170,230, abstract;
10 column 1:25 - 38; column 2:55 - 67; column 3:19 - 35; column 4: 5 - 14; claims 1 and
11 6; and figs. 1, 2, 3, 5 and 7. Nelson's disclosure states that the air flow opening(s) of
12 Nelson's tube "pass the air from the tube to the rear of the mouth and upper trachea."
13 Since Nelson does not disclose any tube structure dorsal of the user's molars, Nelson
14 leaves a reader to guess the path which air traverses after exiting Nelson's tube
15 "approximate the molars." Nelson, U.S. Patent No. 4,170,230, column 1, lines 44 - 47;
16 column 4, lines 5 - 13; and abstract.

17 [0020] Nelson's patents, and especially U.S. Patent No. 4,289,127 (1981), also
18 disclose various cheek-side stabilizing devices including fin-like, wire-like and rod
19 devices. Nelson describes his cheek-side stabilizing devices as rigid or flexible or
20 malleable, but does not describe them as resilient or spring-like.

21 [0021] Pope and Hawkins, U.S. Patent 4,553,549, disclose a "pressure equalization
22 conduit" attached to an orthopedic/orthodontic appliance for treating neuromuscular
23 imbalance which is positioned "so that the tube extends along the outside surface of
24 the teeth around the posterior of the teeth to the position which is in communication
25 with the pharyngeal cavity." Pope, et al., U.S. Patent 4,553,549, specification col.
26 3:10-20 and claim 13. (Pope's "posterior" presumably corresponds to dorsal.) In
27 contrast with Nelson's cheek-side tubes, the pressure equalization conduit of Pope, et
28 al., is not disclosed as a self-contained device designed to stand alone in a cheek
29 pathway. Rather, the Pope conduit is positioned by wire holders that are embedded in
30 the teeth- and palate-engaging elements of the Pope orthopedic/orthodontic device.
31 Pope et al. U.S. Patent 4,553,549, col. 5:60-68. At least one version of the Pope
32 conduit is disclosed and is explicitly claimed as having "inside diameter of from about 2

1 to 3 mm." Pope, Specification, 3:30-40 and claim 16. However, Pope, et al. do not
2 state limiting diameters.

3 Brief Summary of the Invention: BRIEF SUMMARY OF THE INVENTION.

4 [0022] This application discloses a cheek path airway and a cheek pouch anchor. In
5 a preferred version, they are combined with each other, but each also could be used
6 alone or in combination with other prior art devices. Such other prior art devices
7 include jaw control and tongue control devices.

8 [0023] Summary of Cheek Path Airway Invention. The cheek path airway is a hollow
9 tube or channel configured, or adjustable, to act as a conduit for air or other fluids
10 along a user's "cheek pathway." A user's "cheek pathway" is defined more precisely
11 below.

12 [0024] The cheek path airway bypasses nasal airways and provides oral air flow
13 supplemental to nasal flow, even though the user's lips, teeth and jaws are otherwise
14 closed. Thus, the cheek path airway can provide supplemental air volumes to mitigate
15 breathing impairment caused by restriction of a user's nasal airways without a user
16 having to switch to open-mouth breathing.

17 [0025] The cheek path airway's curve from the cheek-side to the dorsal side of a
18 user's rear-most teeth helps constrain rotational and translational motions of the
19 airway tube in a user's mouth. When a user's jaws are opened the cheek path airway
20 alone (without the cheek pocket anchor) remains somewhat vulnerable to rotating or
21 sliding between the biting surfaces of a user's teeth. The airway can be built to
22 mitigate such motions by using a relatively stiff (or stiffly flexible) curve through the
23 user's rear-jaw gap, and by forming (or flexing) the tongue portion of the airway to
24 conform relatively stiffly to the side and roof of the user's rear-mouth cavity, while more
25 rigid portions of the airway extend along the inner wall of a user's cheek and between
26 a user's lips.

27 [0026] The cheek path airway can be made flexible or moldable at strategic positions
28 along its longitudinal axis so that the action of the user's tongue and jaws will press the
29 airway into locations of lesser interference with movements of the user's tongue and
30 rear-jaw gap, thus achieving better fit and stability.

31 [0027] External extensions of the cheek path airway, which curve about the outside
32 comer of a user's mouth and traverse along the user's external cheek wall, can be

1 employed to further constrain the airway in a cheek pathway. Stability can be further
2 improved by an external extension which folds about a user's ear.

3 [0028] A dual cheek path airway, which traverses the two cheek pathways on either
4 side of a user's mouth, can further increase stability as well as increasing air flow
5 volume and providing redundant conduits.

6 [0029] More positive control over destabilizing motions of a cheek path airway can
7 be achieved by combining the cheek path airway with a cheek pouch anchor.

8 [0030] Summary of Cheek Pouch Anchor Invention. The cheek pouch anchor is a
9 spring element which is adapted to be placed within a user's "cheek pouch," an area
10 which lies between the inner wall of a user's cheek and such user's gums and teeth as
11 more precisely defined elsewhere in this disclosure. The cheek pouch anchor of the
12 instant invention can expand and compress in a resilient or spring-like manner within a
13 user's cheek pouch as a user opens and closes the user's jaws. A cheek pouch
14 anchor can better maintain a cheek path airway's positioning while avoiding the more-
15 mobile ventral portions of a user's tongue, avoiding the biting surfaces of the user's
16 teeth, resisting expulsion from the user's mouth, and mitigating risks of choking and
17 gagging.

18 [0031] The cheek pouch anchor invention is capable of receiving joiner to a work
19 piece that is to be positioned at least partially within such user's cheek pouch. The
20 cheek path airway is one type of work piece that can be joined to the cheek pouch
21 anchor.

22 [0032] It is conceived that the cheek pouch anchor could be impregnated or coated
23 with substances that are intended to be released over time within a user's mouth, or it
24 could carry and position containers and other devices at least partially within a user's
25 cheek pouch.

26 [0033] Summary of Combination of Cheek Path Airway and Cheek Pouch Anchor
27 Inventions.

28 [0034] The combination of the cheek path airway and the cheek pouch anchor
29 provides additional constraints upon rotations and translations of the cheek path
30 airway, beyond the constraints built into the cheek path airway itself, which render the
31 combination more suitable for use during sleep.

32 [0035] Summary of Combination of Cheek Path Airway With Existing Jaw- and

1 Tongue-Control Devices. The cheek path airway can be used (with or without the
2 cheek pouch anchor) in combination with a mandibular jaw control device that restricts
3 sagging of a user's mandible toward such user's throat airway during sleep for the
4 purpose of mitigating throat airway impairment and sleep apnea. It is conceived that
5 the cheek path airway also could be used in combination with many other dental, jaw,
6 and tongue control devices. The cheek path airway can functionally leverage itself
7 against a dental device installed in a user's mouth so as to improve the airway's
8 stability within the cheek pathway, but without substantial impairment of the function of
9 such dental device, so that the combination functions cooperatively to mitigate a user's
10 breathing problems.

11 [0036] Some Special Anatomical Definitions. The following definitions have been
12 created for the purposes of this disclosure and the claims:

13 [0037] "User" means the creature using a device, generally a human, though devices
14 in principle could be used by creatures other than humans.

15 [0038] "User's anterior-posterior axis" means head to foot for a human user, head to
16 tail for other creatures. Sometimes also called a "vertical" axis when a human is
17 viewed standing upright.

18 [0039] "User's dorsal-ventral axis" means back to front, that is, with a human user's
19 face in front; such axis is approximately horizontal when an upright human user is
20 viewed. Also sometimes referred to as front and rear.

21 [0040] "User's cheek pathway", sometimes abbreviated to "cheek pathway" or
22 "cheek path", means the pathway, traversing in either direction, from (1) outside the
23 user's mouth, (2) between such user's lips, (3) between such user's inner cheek wall
24 and the cheek-adjacent side of such user's dental arches, gums and teeth, and (4) at
25 least around the cheek-side rear tooth corner of such user's rear-most tooth or teeth
26 from cheek side to dorsal side of such tooth. The cheek pathway can be further
27 extended (5) from the user's cheek-side rear tooth corner through such user's rear-jaw
28 gap, and yet further extended (6) from such user's rear-jaw gap over such user's
29 tongue into the airspace in such user's rear-mouth cavity. The cheek pathway avoids
30 the biting (occlusal) surfaces of a user's teeth.

31 [0041] "User's cheek pouch" lies between the inner wall of one of such user's two
32 cheeks and the cheek-adjacent side of such user's dental arches, gums and teeth. A

1 user's cheek pouch extends along such user's anterior-posterior ("vertical") body axis
2 between the junctures of such user's mandibular and maxillary dental arches with such
3 user's inner cheek wall. Such cheek pouch extends along such user's dorsal-ventral
4 body axis approximately from a user's front teeth to the general area of such user's
5 most-dorsal teeth and rear-jaw gap. The configuration of a user's cheek pouch
6 dynamically alters as the user's jaws and lips open and close. A user has two cheek
7 pouches located on opposing sides of a user's mouth.

8 [0042] "User's cheek-side position" means a location adjacent to a user's inner
9 cheek wall, within the user's cheek pouch, in which a device can be placed.

10 [0043] "User's rear-jaw gap" or "rear-jaw space" means the space remaining open
11 between such user's mandible (lower jaw) and maxilla (upper jaw) dorsally of such
12 user's rear-most tooth or teeth when such user's jaws are closed. The size and shape
13 of the rear-jaw gap will vary from person to person. It is sufficiently large in some
14 persons to accommodate a cheek path airway. Sometimes the rear-jaw gap has been
15 enlarged by extraction of at least one of the person's wisdom teeth. A user's rear-jaw
16 gap also can be artificially enlarged by dental devices which partially block the user's
17 bite and prevent complete closure of the user's jaws. A user generally will have two
18 rear-jaw gaps, one on each side of the user's head.

19 [0044] "Air" as used herein includes any gasses or other fluids for inhalation and
20 exhalation by humans or other creatures. "Air" could include natural environmental air
21 at atmospheric or other pressure and partially or wholly modified gasses and fluids
22 such as supplemental oxygen, mixtures of gasses, aerosols, and oxygenated fluids,
23 whether or not at atmospheric pressure. It is conceived that the cheek path airway
24 could conduct fluids other than "air", including without limitation, pharmaceutical and
25 anesthetic gasses.

26 THE PROBLEMS ADDRESSED BY THE INVENTION.

27 [0045] Nasal air way restriction causes a variety of adverse effects, ranging from the
28 merely uncomfortable to life threatening. The mouth provides an alternate, natural
29 breathing airway, but not when a person's lips are closed.

30 [0046] Many airway devices use a mouth pathway to bypass restricted nasal
31 passages. All airways which use a mouth pathway must be stabilized in the mouth to
32 mitigate risks of gagging and choking and to prevent ejection from the mouth or

displacement within the mouth. These problems of stable positioning of a mouth airway are particularly critical while a user is asleep or otherwise is unconscious. The instant invention mitigates stability problems of stand-alone cheek-side airways. It also mitigates blockage of air flow openings.

[0047] All mouth airway devices must use materials which are essentially non-toxic to the user, and the instant invention is intended to do so.

[0048] Most mouth airway devices are "central mouth" airways which pass between the biting surfaces of a user's teeth. Such devices thus must use some form of bite block to prevent closing of the user's jaws and teeth from crushing the airway. The instant invention can function with or without a bite block in place.

[0049] Many central airway devices are anchored by dental devices that engage the user's teeth or dental arches or palate. Such devices create a potential for undesired orthodontic effects from the airway anchoring and from bite blocking. One orthopedic/orthodontic device is designed to be installed within a user's maxillary dental arch to actively modify a user's mouth anatomy, and it also includes a "pressure equalization conduit" which is positioned in a cheek pathway. Pope et al., U.S. Patent 4,553,549. Use of dental anchoring adds complexity and expense to a cheek path airway device and tends to encumber a user's jaw and tongue movements. It is desirable to have a mouth airway which by-passes, and is not anchored to, a user's teeth or palate.

[0050] The airway of the instant invention bypasses, and is not anchored to, a user's teeth or palate. It avoids the more-mobile ventral portions of a user's tongue and enables the more dorsal portions of a user's tongue to press the airway into positions of lesser interference with the tongue's movements in the user's rear-mouth cavity.

[0051] It can be desirable to preserve some nasal breathing even when nasal passages are restricted. Nasal passages provide a variety of desirable natural breathing features such as filtering, warming and moisturizing the air, and avoidance of high volumes of air flow past teeth, gums and tongue. It also is desirable to have a mouth airway which allows the user's lips to nearly seal about it so as to route air through the airway and avoid open-mouth breathing. Full open mouth breathing causes "dry mouth" discomfort. Because the open mouth provides such a large pathway, open mouth breathing tends to nearly pre-empt nasal breathing, especially if

1 the nasal passages are restricted. Some mouth airway devices aim to function as a
2 complete alternative to nasal breathing while avoiding full open-mouth breathing. For
3 example, Nelson's tube is designed so that "the flow of air therefrom will be
4 approximate to that flow of air as could be expected from normal nasal breathing," (
5 Nelson, U.S. Patent 4,170,230, Abstract).

6 [0052] The instant invention is designed to supplement, but not necessarily to
7 replace, nasal breathing. It thus can help preserve some nasal breathing. It can
8 function during periods of restricted nasal breathing before a user has switched from
9 closed-mouth nasal breathing to open-mouth breathing.

10 [0053] Problems with Cheek-side Positioning of Airways.

11 [0054] Some mouth airways, herein called "cheek-side" airways, are designed for
12 placement between the inner wall of a user's cheek and a user's cheek-adjacent gums
13 and teeth in order to avoid the biting surfaces of a user's teeth and the user's tongue.
14 This "cheek-side" location is only a portion of what is defined in this disclosure as a full
15 "cheek pathway". The Nelson airways, U.S. Patents No. 4,170,230, (1979),
16 4,261,354 (1981), 4,262,666 (1981) and 4,289,127 (1981), for example, are designed
17 to lie in a cheek-side position.

18 [0055] Cheek-side Air-flow Openings Subject to Blockage and Saliva Drainage. Air-
19 flow openings placed in a cheek-side position are subject to blockage by the user's
20 cheek, gum and tooth tissues and by mouth liquids. They also tend to drain liquids
21 into the airway tube and out of the user's mouth. As a result, there is a relatively small
22 margin for error in cheek-side positioning of air flow openings.

23 [0056] A user's inner cheek wall naturally, resiliently drapes over the cheek-adjacent
24 side of a user's dental arches, teeth and gums. It will tend to drape over an airway
25 device in a cheek-side position, urging the airway against the user's dental arches,
26 gums and teeth. This draping effect can cause blockage of cheek-side air flow
27 openings by the user's tissues, but the draping effect also provides forces that can be
28 utilized to stabilize cheek-side devices.

29 [0057] The instant invention mitigates blockage of air flow openings by curving the
30 cheek path airway around the user's rear-tooth corner from cheek side to dorsal side.
31 This curve either exposes the airway's internal open tip to the user's rear-jaw gap, or,
32 preferably, enables projection of the airway's internal open tip through the user's rear-

1 jaw gap and over the user's tongue within the airspace in the user's rear-mouth cavity.
2 The larger airspace volume within a user's rear-mouth cavity provides a larger margin
3 of error in placement of air flow openings than does a cheek-side positioning of air flow
4 openings adjacent to a user's teeth and gums. This positioning also tends to mitigate
5 exposure of the tube opening to saliva and other mouth liquids.

6 [0058] Slippage and Rotation Problems of Cheek-side Airways.

7 [0059] Cheek-side airways have numerous modes of potentially undesirable motion,
8 including the three axes of translational motions (anterior-posterior, dorsal-ventral, and
9 side-to-side or "lateral"), as well as the three modes of rotational motion (roll, pitch and
10 yaw).

11 [0060] Undesirable motions of a cheek-side airway include: slippage of the device
12 between the biting surfaces of a user's teeth; interference with the user's tongue
13 motions; slippage into gagging or choking positions; dorsal-ventral slippage of the
14 device between the user's lips, and expulsion from the user's mouth.

15 [0061] In Nelson's tubes, for example, undesirable rotation of the tube caused
16 blockage of air openings by the user's mouth tissues. Nelson's tubes also were
17 subject to dorsal-ventral slippage. Nelson, U.S. Patent 4,289,127, col. 1:35-45.
18 Nelson developed cheek-side stabilizing devices to mitigate undesirable rotational
19 motions (see particularly U.S. Patent 4,289,127), as well as to prevent dorsal-ventral
20 slippage and impairment of the user's lip seal (see U.S. Patents 4,170,230, 4,261,354,
21 4,262,666, 4,275,725, and 4,289,127).

22 [0062] Fixed-span cheek-side stabilizing devices, such as the fin-like, wire-like and
23 rod devices of Nelson, have a potentially disabling instability problem. Such fixed-
24 span devices cannot dynamically adjust to maintain a span across the gap (inter
25 occlusal space) created between a user's maxillary and mandibular teeth as the user's
26 jaws open. However, a user's jaws sometimes can open beyond that fixed-span
27 height, allowing the fixed-span device to rotate or slip between the biting (occlusal)
28 surfaces of the user's teeth.

29 [0063] Suppose, by way of hypothetical illustrative example, that the heights of a
30 user's mandibular and maxillary dental arches are 1.75 cm each (measured from their
31 respective junctures with the user's inner cheek wall to the biting surfaces of their
32 respective teeth). The vertical height of such user's cheek pocket, when the user's

1 jaws are closed, is the sum of the heights of the user's dental arches, that is, 3.5 cm.
2 The height of the user's cheek pocket with jaws closed establishes the maximum
3 vertical span of a fixed-span cheek-side stabilizing device because a greater fixed
4 span would block full closure of the user's jaws. Whenever the user is capable of
5 opening an inter occlusal space which exceeds the 1.75 cm height of one of the user's
6 dental arches then the potential will exist for a fixed-span cheek-side stabilizing device
7 to rotate or translate between the biting surfaces of such user's teeth. Suppose the
8 user's jaws open an inter occlusal space of 2 cm. Then the sum of that 2 cm inter
9 occlusal space and the 1.75 cm height of one dental arch will total 3.75 cm, which
10 exceeds the 3.5 cm maximum fixed span of a cheek-side stabilizing device that would
11 permit that user's jaws to fully close, thereby potentially permitting a fixed-span
12 stabilizing device to slip or rotate into that 2.0 cm inter occlusal space. Such an inter
13 occlusal space might occur, for example, during a yawn or a cough. Of course, the
14 hypothetical dimensions used above would vary from user to user, but the principle
15 should apply to many potential users.

16 [0064] The instant invention's solution to the instability problem of fixed-span cheek-
17 side positioning devices is to use a spring which resiliently expands and compresses
18 within the user's cheek pouch as the user's jaws open and close. The expansion of
19 the resilient cheek pouch anchor of the instant invention when a user's jaws open can
20 usefully increase the stability of a cheek-side airway over that of a fixed-span cheek-
21 side stabilizing device even if the resilient device is unable to expand the full vertical
22 height of a user's maximum jaw opening. This is because most jaw openings are less
23 than the maximum potential jaw opening.

24 [0065] Lip-Sealing Problems.

25 [0066] Cheek-side airway tubes pass between a user's lips and thus can break the
26 seal of the user's lips, permitting air passage around rather than through the tube.
27 This lip sealing problem tends to increase with increasing tube diameter and certain
28 variant shapes. There are many prior art lip-sealing devices.

29 [0067] Mouth-Corner Flanges. Nelson's patents, and especially U.S. Patents
30 4,170,230 and 4,275,725, disclose modifications of Nelson's tube by flanges which
31 engage the corner of a user's mouth and the user's lips for purposes of stabilizing the
32 tube and sealing the user's lips.

1 [0068] Lip-conforming Tube Shapes. It is known that use of a tube lip portion which
2 has an oval or somewhat flattened radial cross-section can improve sealing of the
3 user's lips. That known solution can be employed in the instant invention.

4 OBJECTIVES AND FEATURES OF THE INVENTION.

5 [0069] Objectives of this invention include the following:

6 [0070] An objective of this invention is to provide a relatively stable, supplemental
7 ventilation pathway through a user's closed lips to the rear of the user's oral cavity
8 which will remain open during closed-mouth, nasal breathing.

9 [0071] An objective of this invention is to provide supplemental air to a user's throat
10 when a user's lips otherwise remain closed for the purpose of mitigating adverse
11 effects of restricted nasal airways without requiring that the user switch from closed-
12 mouth nasal breathing to open-mouth breathing.

13 [0072] An objective of this invention is to provide an airway passing from external air
14 through a user's otherwise-closed lips to the rear of the user's oral cavity, while by-
15 passing the user's jaws, tooth biting surfaces, and much of the user's tongue, including
16 the more mobile forward portions of the user's tongue. In particular, it is an objective
17 of this invention to provide an airway which can stabilize itself within in a user's cheek
18 pathway without anchoring to a user's teeth, thus permitting opening and closing of the
19 user's jaws without disruption of the airway's cheek pathway positioning.

20 [0073] An objective of this invention is that it not physically prevent or restrict a user
21 from switching from closed-mouth nasal breathing to open-mouth breathing.

22 [0074] It is an objective of this invention that it provide one or more passive air ways
23 past closed lips which will remain relatively stable in a sleeping person,
24 notwithstanding lip, jaw and tongue motions.

25 [0075] It is an objective of this invention that it have a shape and be positioned so as
26 to minimize gagging or choking risk to a user of this invention, particularly while
27 sleeping.

28 [0076] It is an objective of this invention that it remain relatively resistant to blockage
29 of air flow openings by the cheek wall, gums, teeth, tongue or other tissue in a user's
30 mouth.

31 [0077] It is an objective of this invention that it be capable of being placed so that it
32 minimizes transmission of saliva or other mouth liquids through the airway past a

1 user's lips.

2 [0078] It is an objective of this invention that it mitigate the "dry mouth" distress
3 which many persons experience with open-mouth breathing by supplementing and
4 preserving closed-mouth nasal breathing. It is an objective of this invention to deliver
5 supplemental air directly to the rear of a user's oral cavity with a user's lips otherwise
6 closed, minimizing air currents in more ventral portions of a user's mouth.

7 [0079] It is an objective of this invention that lay persons be capable of inserting,
8 adjusting, using, and removing it by themselves.

9 [0080] It is an objective of this invention that it be adjustable to fit a particular user's
10 comfort.

11 [0081] It is an objective of this invention that it be sanitizable by the same processes
12 used for ordinary household eating utensils, such as dishwashing machines, or by the
13 processes used for artificial dentures.

14 [0082] It is an objective of this invention to provide a supplemental air way to the rear
15 of a user's mouth cavity which can function in combination with devices designed to
16 control a user's tongue, tooth and/or jaw position, so the combination can
17 cooperatively mitigate impaired breathing due to restriction of the user's nasal and
18 throat airways. It also is an objective that the airway be compatible, and function in
19 combination, with an anti-bruxing dental device. One useful effect, where such jaw-
20 control or anti-bruxing devices block full closing of a user's jaws, is that such devices
21 can increase the cross-sectional area of a user's rear-jaw gaps which thereby more
22 easily accommodate a larger diameter cheek path airway.

23 [0083] Jaw-control and Tongue-Control Devices.

24 [0084] Examples of existing intra-oral, jaw-control and tongue-control devices with
25 which it is conceived the invention might be used in combination (perhaps requiring
26 some modification) are:

27 Fenton, U.S. Pat. No. 5,499,633; Halstrom, U.S. Pat. No. 5, 868,138; Strong, U.S. Pat.
28 No. 6,418,933; Thornton, U.S. Pat. No. 6325,064 B1; Meade, U.S. 6,055,986; Belfer,
29 U.S. Pat. No. 6,092,523; Frantz, U.S. Pat. No. 6,109,625; Bergersen, U.S. Pat. No.
30 6,129,084; Thornton, U.S. Pat. No. 6,155,262; David, U.S. No. 6,450,167 B1;
31 Tielmans, U.S. Pub. No. 2001, 0027793 A1 and U.S. Pat. No. 6,408,852 B2; Gaskell,
32 U.S. Pub. No. 2002/0000230 A1; and Dort, Pub. No. US 2002/0117178 A1 (Aug.

2002). See also Thornton, U.S. Pat. No. 6,209,542 (nasal mask combined with dental device). Wagner, U.S. Patent 5,566,684 (1996) discloses a mouthguard which a user can self-fit to the user's maxillary dentition to mitigate nocturnal teeth grinding. An embodiment of Wagner's device, with instructions for self-fitting by users, is marketed under the trade name "The Doctor's Night Guard", by Dental Concepts, Paramus, N.J., USA. There are advantages where a cheek-path airway is physically separated from the jaw-control and tongue-control devices, but designed to be used in a user's mouth in combination with such devices. The cheek-path airway then can be inserted or removed separately from the jaw- or tongue-control device, enabling separate handling of the cheek-path airway and such devices, such as separate fitting, adjustment, cleaning, and replacement. Moreover, it is conceived that existing jaw- and tongue-control devices which do include built-in airways could be simplified, and thus more readily constructed, if such built-in airways are deleted and their function replaced by a physically separate cheek-path airway adapted for combination use with such modified devices.

BRIEF DESCRIPTION OF DRAWINGS **BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS.**

[0085] Figure 1 is an elevation view of a cheek path airway combined with a cheek pouch anchor.

[0086] Figure 2 is an elevation view of the same cheek path airway combined with a cheek pouch anchor, as is Figure 1, but folded.

[0087] Figure 3 is an elevation view of the side of a user's face showing a section view of the user's mouth, along Section 3-3 of Figure 3A, with the user's cheek removed, showing placement of a cheek path airway combined with a cheek pouch anchor.

[0088] Figure 4 is a section view, along section 4-4 of Figure 4A, looking upward at the user's maxillary teeth and jaw with cheek path airways in place.

[0089] Figure 5 is a perspective view of a cheek path airway and cheek pouch anchor approximately positioned relative to a dental device.

[0090] Figure 6 is a perspective view of a dual cheek path airway folded into the approximate shape for placement in a user's cheek pathways.

[0091] Figure 7 is a view of the same dual cheek path airway as in Figure 6, but

1 showing the airway in-line, with a zero curvature along its longitudinal axis, as
 2 manufactured but before folding the airway to fit a user's mouth.

3 [0092] Figure 8 is a perspective view of a dual cheek path airway placed in cheek
 4 pathways in a user's mouth.

5 [0093] Figure 9 is a second perspective view of a dual cheek path airway placed in
 6 cheek pathways in a user's mouth.

7 [0094] Figure 10 is an elevation view of a user's face showing external airway
 8 stabilizing devices in place.

9 [0095] Figure 11 is a perspective view of a user's face with mouth open, showing a
 10 dual cheek path airway with external stabilizing extensions in place.

11 [0096] Figure 12 is a perspective view, from the upper left front, of a dual cheek path
 12 airway approximately positioned about an inverted (upside down), articulated, dental
 13 jaw-control device.

14 [0097] Figure 13 is a perspective view, from the upper rear, of an articulated, prior
 15 art, dental jaw-control device.

16 [0098] Figure 14 is a plan view of an inverted (upside down) dental jaw-control
 17 device with two single-cheek versions of the airway approximately positioned about it.

18 [0099] Figure 15 is an elevation view of the side of a user's face, showing a section
 19 view along section 15 - 15 of Figure 15A with the user's cheek removed, and showing
 20 a cheek path airway placed about a dental jaw-control device in the user's mouth.

21 Table of Drawing Elements

22		
23	[0100]	Cheek Path Airway Elements
24	[0101]	1 external open tip of hollow tube, to be positioned external to user's lips
25	[0102]	1a external open tip on second end of hollow tube in dual-cheek version of
26		airway
27	[0103]	2 lip portion of hollow tube, for traversing between user's lips
28	[0104]	2a second lip portion of hollow tube in dual-cheek version of airway
29	[0105]	3 cheek-side portion of hollow tube, to be positioned between inner side of
30		user's cheek and cheek-adjacent (buccal) side of user's teeth and gums
31	[0106]	3a second cheek-side portion of hollow tube in dual-cheek version of airway
32	[0107]	4 rear-tooth corner portion of hollow tube; curved, or flexible, transition

1 from cheek-side portion to jaw-gap portion of hollow tube, adjacent to
2 rear-most tooth.

3 [0108] 4a rear-tooth corner portion, curved, or flexible, transitioning from cheek
4 portion to jaw-gap portion of hollow tube, adjacent to rear-most tooth in
5 dual cheek version of airway.

6 [0109] 5 rear-jaw gap portion of hollow tube (may be straight, or curved, or
7 flexible)

8 [0110] 5a Second rear-jaw gap portion of hollow tube in dual cheek version of
9 airway.

10 [0111] 6 Tongue portion of hollow tube, to extend from rear-jaw gap over user's
11 tongue into user's rear mouth cavity (may be straight, or curved, or
12 flexible).

13 [0112] 6a Second tongue portion of hollow tube in dual cheek version of airway.

14 [0113] 7 Rear-mouth cavity-spanning portion of hollow tube in dual cheek version
15 of airway; joins first and second cheek-side portions 8 and 9 of dual
16 cheek version.

17 [0114] 8 First cheek-side portion of hollow tube in dual cheek version of airway, to
18 traverse user's first cheek pathway on first side of user's mouth

19 [0115] 9 Second cheek-side portion of hollow tube in dual cheek version of
20 airway, to traverse user's second cheek pathway on second side of
21 user's mouth.

22 [0116] 10 air flow opening in first position in wall of external end of hollow tube

23 [0117] 10a air flow opening in first position in wall of second external end of hollow
24 tube in dual cheek version

25 [0118] 11 air flow opening in second position in wall of external end of hollow tube

26 [0119] 11a air flow opening in second position in tube wall of second external end of
27 hollow tube in dual cheek version.

28 [0120] 12 air flow opening in first position in tube wall of tongue portion of hollow
29 tube (tube portion 6)

30 [0121] 12a air flow opening in first position in tube wall of second tongue portion of
31 hollow tube (tube portion 6a) in dual cheek version

32 [0122] 13 Air flow opening in second position in tube wall of tongue portion of

1 hollow tube.

2 [0123] 13a Air flow opening in second position in tube wall of second tongue portion

3 of hollow tube in dual cheek version.

4 [0124] 14 Air flow opening in third position in tube wall of tongue portion near the

5 center of the rear-mouth cavity in single cheek version of airway;

6 alternately, located in hollow tube portion 7 in dual cheek version of

7 airway.

8 [0125] 15 Air flow opening in wall of hollow tube, in fourth position in tongue portion

9 of hollow tube near the center of the rear-mouth cavity in single cheek

10 version of airway; alternately, located in hollow tube portion 7 in dual

11 cheek version of airway.

12 [0126] 16 internal open end of hollow tube, located on tongue portion of hollow

13 tube in single cheek version of airway, to be projected within airspace in

14 user's rear-mouth cavity.

15 [0127] 16a internal open end of second hollow tube, located on second

16 tongue portion of second hollow tube in user's second cheek

17 pathway, when two single cheek versions used in opposite

18 cheeks.

19 [0128] 17 lacing holes in cheek-side portion of hollow tube, adapted to receive

20 flexible, resilient filament 28 of cheek positioning device.

21 [0129] 18 reserved

22 [0130] 19 reserved

23

24 [0131] Airway Retainer Elements

25 [0132] 20 a first type of retainer on external end of hollow tube

26 [0133] 21 reserved

27 [0134] 22 a second type of retainer, mouth-corner portion of hollow tube, to curve

28 from lip portion 2 of tube about corner of user's mouth to outside wall of

29 user's cheek

30 [0135] 23 External cheek-side extension of hollow tube.

31 [0136] 24 Flexible (or curved) portion of external cheek-side extension of tube

32 [0137] 25 Flexible (or curved) ear piece of external extension of tube

1 [0138] 26 Finger grip portion of ear piece.

2 [0139] 27 Tape site on external cheek-side extension of hollow tube, for taping tube

3 to user's face.

4

5 [0140] Cheek Pouch Anchor Elements

6 [0141] 28 Flexible, resilient filament

7 [0142] 28a First (upper) loop in laced filament

8 [0143] 28b second (upper) loop in laced filament

9 [0144] 28c third (lower) loop in laced filament

10 [0145] 28d fourth (lower) loop in laced filament

11 [0146] 29 First curled (or crimped) end of filament

12 [0147] 29a Second curled (or crimped) end of filament

13

14 [0148] User's Body Parts

15 [0149] 30 user's upper lip

16 [0150] 31 user's lower lip

17 [0151] 32 inner wall of user's first cheek

18 [0152] 32a inner wall of user's second cheek

19 [0153] 33 user's upper (maxillary) rear-most (dorsal) tooth on first side of user's

20 mouth

21 [0154] 33a user's upper (maxillary) rear-most (dorsal) tooth on second side of user's

22 mouth

23 [0155] 34 lingual (tongue) side of user's rear-most upper (maxillary) tooth on first

24 side of user's mouth

25 [0156] 34a lingual (tongue) side of user's rear-most upper (maxillary) tooth on

26 second side of user's mouth

27 [0157] 35 buccal (cheek-adjacent) side of user's rear-most upper (maxillary) tooth

28 on first side of user's mouth

29 [0158] 35a buccal (cheek-adjacent) side of user's rear-most upper (maxillary) tooth

30 on second side of user's mouth

31 [0159] 36 user's upper jaw (maxilla) on first side of user's mouth

32 [0160] 36a user's upper jaw (maxilla) on second side of user's mouth

1 [0161] 37 user's lower jaw (mandible) on first side of user's mouth
 2 [0162] 38 user's rear-most (dorsal) lower (mandibular) tooth on first side of user's
 3 mouth.
 4 [0163] 39 user's tongue
 5 [0164] 40 roof of user's rear-mouth (oral) cavity
 6 [0165] 41 airspace in user's rear-mouth (oral) cavity
 7 [0166] 42 user's rear-jaw gap on first side of user's mouth
 8 [0167] 42a user's rear-jaw gap on second side of user's mouth
 9 [0168] 43 Occlusal (biting) surface of user's tooth.
 10 [0169] 44 User's ~~palatal tonsil~~ uvula (depending from user's soft palate)
 11 [0170] 45 First corner of user's mouth (at juncture of upper and lower lips).
 12 [0171] 45a Second corner of user's mouth.
 13 [0172] 46 External wall of user's first cheek
 14 [0173] 47 User's first ear
 15 [0174] 48 Lower side of user's first ear
 16 [0175] 49 Upper side of user's first ear
 17 [0176] 50 Dotted approximate outline of user's cheek pouch (showed with user's
 18 ~~cheek-wall~~ removed)
 19
 20 [0177] Dental Device Elements
 21 [0178] 51 upper (maxillary) portion of dental device (showed upside down in some
 22 drawings)
 23 [0179] 52 lower (mandibular) portion of dental device (showed upside down in
 24 some drawings)
 25 [0180] 53 female (or sleeve) portion of adjustable strut of dental device
 26 [0181] 54 male (or arm) portion of adjustable strut of dental device
 27 [0182] 55 pivot bolt for mounting adjustable strut in maxillary portion of dental
 28 device
 29 [0183] 56 pivot bolt for mounting adjustable strut in mandibular portion of dental
 30 device
 31 [0184] 57 collar of male (arm) portion of adjustable strut of dental device
 32 [0185] 58 collar of female (sleeve) portion of adjustable strut of dental device

- 1 [0186] 59 wire reinforcing frame embedded in lower (mandibular) portion of dental
2 device.
- 3 [0187] 60 wire reinforcing frame embedded in upper (maxillary) portion of dental
4 device.
- 5 [0188] 61 series of teeth-engaging balls mounted on wire reinforcing frame 33 and
6 projecting out of body of mandibular portion of dental device
- 7 [0189] 62 channel fitted to user's mandibular teeth
- 8 [0190] 63 channel fitted to user's maxillary teeth
- 9 [0191] 64 dental device, with channel fitted to user's teeth

10 DETAILED DESCRIPTION OF ~~DRAWINGS~~ THE INVENTION

- 11 [0192] Figure 1 shows a cheek path airway combined with a cheek pouch anchor.
12 The cheek path airway is formed of a hollow tube (showed as manufactured in-line,
13 with approximately zero curvature along its longitudinal axis), having external open tip
14 1, lip portion 2, cheek-side portion 3, flexible rear-tooth corner portion 4, rear-jaw gap
15 portion 5, tongue portion 6, air flow openings 10 and 11 in the tube wall placed
16 adjacent to external open tip 1, and air flow openings 14 and 15 in the tube wall placed
17 adjacent to internal open tip 16, with lacing holes 17 through the walls of the cheek-
18 side portion 3 of the hollow tube. Figure 1 also shows flexible, resilient filament 28,
19 slidably laced through lacing holes 17 of the hollow tube, to form upper first loop 28a,
20 upper second loop 28b bearing upper curled loop end 29, lower third loop 28c, and
21 lower fourth loop 28d bearing lower curled loop end 29a. Loops 28a, 28b, 28c and
22 28d combine [t] to form the whole loop span formed by the flexible, resilient filament
23 28. By tugging on curled loop ends 29 and 29a a user can lengthen loops 28b and
24 28d and shorten loops 28a and 28c; conversely, by tugging on loops 28a and 28c a
25 user can lengthen those loops while shortening loops 28b and 28d, thus enabling a
26 user to adjust the whole loop span of filament 28 for better fit.
- 27 [0193] Figure 2 shows the same cheek path airway combined with a cheek pouch
28 anchor as in Figure 1, but with the flexible rear tooth-corner portion 4 folded for
29 positioning in a user's cheek pathway.
- 30 [0194] Figure 3 depicts a cheek path airway combined with a cheek pouch anchor
31 and placed in a user's cheek pathway and cheek pouch. Figure 3 shows the hollow
32 tube airway with external open end 1 in a position outside the user's lips, and lip

portion 2 passing between the user's upper lip 30 and lower lip 31. Figure 3 shows cheek-side portion 3 of the hollow tube lying adjacent to the buccal side of the user's teeth, with rear-tooth corner portion 4 of the hollow tube flexed about the user's rear-most (dorsal) upper tooth 33 and lower tooth 38. It shows airway rear-jaw gap portion 5 passing through user's jaw gap 42, adjacent to user's tongue 39. It shows flexible, resilient filament 28 laced through lacing holes 17 in cheek-side portion 3 of the hollow tube, and placed within the user's cheek pouch which is approximately outlined by the dotted line 50.

[0195] Figure 4 depicts a section view, along section 4-4 of Figure 4A, looking upward at a user's upper (maxillary) jaw and teeth. It shows two variants of the single-cheek version of the airway placed in the user's two cheek pathways on opposing sides of a user's mouth. In the user's first cheek pathway, in the lower part of the drawing, the hollow tube has external open end 1, with added mouth-corner portion 22 flexed to curve about the corner of the user's mouth to act as a retainer element, external cheek-side portion 23 bearing a tape site 27 for taping the tube to a user's cheek, and air flow opening 11. Lip portion 2 of the hollow tube passes the user's upper lip 30, cheek-side portion 3 passes between the user's inner cheek wall 32 and the buccal side of the user's teeth and gums, with rear-tooth corner portion 4 of the hollow tube flexed about the user's rear-most (dorsal), upper (maxillary) tooth 33, which tooth has a lingual side 34. Rear-jaw gap portion 5 of the hollow tube passes user's upper jaw (maxilla) 36 through the user's rear-jaw gap 42. Tongue section 6 of the hollow tube projects internal open end 16 of the hollow tube into the airspace 41 in the user's rear-mouth cavity. Adjacent to internal open end 16 is air flow opening 14 in the wall of the hollow tube. The upper portion of Figure 4 shows the user's second cheek pathway with a second airway in place. The second airway is modified with retainer 20 placed adjacent to the external open tip 1a, positioned outside of user's upper lip 30.

[0196] Figure 5 depicts a cheek path airway approximately positioned about a dental device 64 which has a channel 62 to engage a user's lower teeth (or 63 if engaging user's upper teeth). The dental device 64 can be used to expand a user's rear-jaw gap, while also performing other functions such as an anti-bruxing device.

[0197] Figures 6 and 7 are comparative depictions of the same dual cheek path

1 airway, except that in Figure 7 the airway's longitudinal axis has approximately zero
2 curvature, as manufactured in-line. By comparison, in Figure 6 the airway has been
3 folded after manufacture to approximate the shape necessary to fit into the cheek
4 pathways in a user's mouth. Figures 6 and 7 show a hollow tube having external open
5 end 1 and adjacent air flow openings 10 and 11 in the tube wall; lip portion 2; cheek-
6 side portion 3; rear-tooth corner portion 4; rear-jaw gap portion 5; tongue portion 6 with
7 flexible joints and with air flow opening 12 in the tube wall; and rear-mouth-cavity
8 spanning portion 7 with air flow opening 15 in the tube wall. In the dual cheek path
9 airway the rear-mouth-cavity spanning portion 7 joins first cheek-side portion 8
10 (comprised of portions 1 through 6) with second cheek-side portion 9 (comprised of
11 portions 1a through 6a).

12 [0198] Figure 8 depicts a user's gaping mouth with a dual cheek path airway
13 approximately placed. The view looks at a slight upward angle towards the user's
14 upper teeth including rear-most tooth 33 having lingual side 34 and buccal side 35 with
15 rear-tooth corner portion 4 curved about rear-most tooth 33. Figure 8 depicts rear-jaw
16 portion 5 of the airway passing through the user's rear-jaw gap 42. It also depicts
17 airway portions 6 and 7, with air flow openings 12 and 14 positioned above the user's
18 tongue 39, in the airspace 41 of the user's rear-mouth cavity adjacent the roof 40 of
19 the user's mouth, ventrally of the user's ~~palatal tonsil~~ uvula 44. The depicted
20 placement of the cheek path airway is somewhat distorted, relative to the user's mouth
21 parts, from where the airway would typically lie when the user's mouth is in a less
22 gaping position.

23 [0199] Figure 9 is the same as Figure 8 except that the view is at a slightly more
24 downward angle enabling a view of the user's lower teeth and a less obstructed view
25 of the rear of the user's mouth, including ~~palatal tonsil~~ uvula 44. This view also
26 somewhat distorts the positioning which the airway would have relative to the user's
27 mouth parts if the user's mouth were in a less gaping posture.

28 [0200] Figure 10 shows a front and side perspective view of a user's face with a dual
29 cheek path airway in place and the user's lips closed. The airway projects out through
30 the user's lips, near the corners 45 and 45a of the user's mouth, with external air flow
31 opening 10 adjacent to the user's lips. The second type of retainer, mouth-corner
32 portion 22 of the hollow tube, curves about the corner 45 of the user's mouth. External

1 cheek-side extension 23, having flexible joint portion 24, lies along the outside of the
2 user's cheek 46. Flexible ear piece 25 is curved about the lower side 48 and the upper
3 side 49 of the user's ear 47, and the airway's ear piece 25 terminates in finger grip
4 portion 26.

5 [0201] Figure 11 depicts a user's face and open mouth with a dual cheek airway in
6 place, where the airway has external stabilizing parts, including mouth-corner portion
7 22, external cheek-side extension 23 with flexible joint 24, and ear piece 25 with finger
8 grip portion 26.

9 [0202] Figure 12 depicts a frontal and side perspective view of a dual cheek path
10 airway folded about a dental jaw-control device in a very rough approximation of the
11 relationship that the airway would have to the dental device in a user's mouth, with the
12 airway passing behind the dental device and around the outside of the struts of the
13 dental device. For convenience the dental device is depicted upside down and is
14 articulated to better display its parts. The dental device has a mandibular (lower jaw)
15 portion 52 and a maxillary (upper jaw) portion 51, which are connected by adjustable
16 struts on either side. The struts have female (sleeve) portion 53 which slidably receives
17 male (arm) portion 54. The struts have collars 57 and 58 which are rotatably mounted
18 on pivot bolts 55 and 56. Pivot bolt 55 is rigidly mounted near the dorsal end of
19 maxillary portion 51, and pivot bolt 56 is rigidly mounted near the ventral end of
20 mandibular portion 52. Mandibular portion 52 and maxillary portion 51 typically are
21 formed of plastic cast in molds imprinted by a user's mandibular and maxillary teeth.
22 Wire reinforcing frames 59 and 60, as well as seats for pivot bolts 55 and 56, are
23 embedded in the plastic casts which form mandibular portion 52 and maxillary portion
24 51. The embedded reinforcing wire frames 59 and 60 are visible because the plastic in
25 which they are embedded is clear. Figure 12 depicts the dual cheek path airway with
26 flexible rear-tooth corner portion 4 of the airway folded to project cheek-side portion 3
27 around the outside of the strut of the dental device, and to project rear-jaw-gap-~~portions~~
28 portion 5 of the airway about the dorsal-~~corners corner~~ of the dental device. Flexible
29 joints in tongue portion 6 and rear-mouth-cavity spanning portion 7 of the airway curve
30 about the dorsal side of the dental device.

31 [0203] Figure 13 depicts from a dorsal perspective the same dental jaw-control device
32 as that depicted in Figures 12 and 13 in combination with cheek path airways. The

1 dental device is depicted upside down to expose the teeth-engaging channel 62 of
2 mandibular portion 52 which is cast from a mold of a user's mandibular teeth. The
3 embedded wire reinforcing frame projects a series of teeth-engaging balls 61 out of the
4 plastic cast adjacent to the buccal wall of teeth-engaging channel 62. Figure 13 also
5 depicts another view of the wire reinforcing frame 60 embedded in the clear plastic cast
6 which forms maxillary portion 51 of the dental device. The entire dental jaw-control
7 device depicted in Figure 13 is prior art, but is depicted in order to show additional
8 aspects of the dental device with which the cheek path airway can be combined.

9 [0204] Figure 14 is a plan view depicting two single-cheek versions of the airway
10 approximately positioned about the same dental jaw-control device as is depicted in
11 Figures 12 and 13. Figure 14 shows rear-tooth corner portion 4 of the airway flexed
12 about the dorsal corner of the dental device, projecting rear-jaw gap portion 5 and
13 tongue portion 6 of the airway about the dorsal side of the dental device and projecting
14 cheek-side portion 3 around the outside of the struts of the dental device, in
15 approximately the positions which the airways would have relative to the dental device
16 when both are in place in a user's mouth with the user's jaws closed.

17 [0205] Figure 15 is a side view of a user's face, along section 15 - 15 of Figure 15A,
18 with the user's cheek removed. It shows a cheek path airway placed in a user's cheek
19 pathway so as to operate cooperatively with a dental jaw-control device which also is in
20 place in the user's mouth. Maxillary portion 51 of the dental device is engaging the
21 user's maxillary teeth and mandibular portion 52 is engaging the user's mandibular
22 teeth, with pivot bolt 56 disposed more ventrally on mandibular portion 52 and pivot bolt
23 55 disposed more dorsally on maxillary portion 51 so that the user's mandibular jaw is
24 urged ventrally relative to the user's maxillary jaw. The purpose is to prevent the user's
25 mandibular jaw from sagging dorsally towards the user's throat when the user is lying
26 more or less supine during sleep. The dental device also can serve an anti-bruxing
27 function. A cheek path airway is placed around the dental device with cheek-side
28 portion 3 of the airway positioned outside the strut (sleeve 53 and arm 54) of the dental
29 device. The rear-tooth corner portion 4 of the airway curves about the dorsal corner of
30 the dental device, and rear-jaw gap portion 5 of the airway projects dorsally of the
31 dental device. In this configuration the user can open and close the user's jaws,
32 operating the slidable sleeve 53 and arm 54 of the dental device while the collars of the

1 strut rotate about pivot bolts 55 and 56. When placed in a cheek pathway the inner wall
2 of the user's cheek (not shown in Figure 15) drapes over and presses against the
3 relatively rigid cheek-side portion 3 of the airway while the relatively rigid lip portion 2 of
4 the airway projects between the user's lips 30 and 31. Pressure of the user's inner
5 cheek wall and mouth corner (not shown in Figure 15) urges portion 3 of the airway
6 against the strut (sleeve 53 and arm 54) of the dental device, helping constrain pitch
7 and yaw rotation of the airway. Sleeve 53 and arm 54 of the dental device also prevent
8 cheek-side portion 3 of the airway from slipping laterally between the maxillary and
9 mandibular portions 51 and 52 of the dental device when the user's jaws open.

11 Preferred Embodiments of Invention.

12 [0206] Airway Tube. In a preferred version, the cheek path airway is formed as a
13 relatively rigid tube with flexible joints interspersed at strategic positions along the
14 tube's longitudinal axis. The more rigid sections of the tube provide structural stability
15 and better leverage to avoid the biting surfaces of a user's teeth, as well as to better
16 project the internal and external open ends of the airway into desirable locations. By
17 reference to Figures 3, 4, Figures 3, 4, 8, 9, 10, 11 and 15, the user's inner cheek wall
18 (labeled 32 in Figure 4, not shown in Figures 3 and 15); drapes over and provides
19 cheek-side pressure upon cheek-side portion 3 which is relatively rigid along the
20 longitudinal axis. In Figures 3, 3A, 8, 9, 10, 11, 15 and 15A the user's inner cheek walls
21 are not visible and labeled but may be inferred from human anatomy. The user's
22 mouth corners 45 and 45A, labeled in Figure 10, and the user's lips 30 and 31 can
23 drape about airway portions 2 and 2A as depicted in Figures 3, 8, 9, 10, 11 and 15.
24 Figure 4, a schematic, is not drawn to scale but rather exaggerates spacing between
25 the user's inner cheek walls 32 and 32A and airway cheekside portions 3 and 3A in
26 order to more clearly delineate the airway structure from the user's mouth tissues. By
27 reference to Figure 15 the draping effect of the user's cheek (not shown) urges cheek-
28 side portion 3 against sleeve 53 and arm 54 of the strut of the dental device,
29 constraining rear-tooth corner portion 4 and rear-jaw gap portion 5 of the tube from
30 yawing into the inter occlusal space between mandibular portion 52 and maxillary
31 portion 51 of the dental device. By reference to Figure 3, the draping effect of the
32 user's cheek (not shown) presses against both rigid cheek-side portion of the airway

and against the cheek pouch anchor, again constraining yawing of rear-tooth corner portion 4 and rear-jaw gap portion 5.

[0207] In-Line Manufacture of Airway Tube. The airway tube, including the flexible joints, preferably is manufactured "in-line," that is, with near-zero curvature in the longitudinal axis of the tube, as in Figures 1 and 7. Such near-zero curvature during manufacture will ease manufacture, packaging, transportation, storage and retail display of the airway, while the interspersed flexible joints enable a user to shape the tube along its longitudinal axis to fit the user's mouth, as in Figures 1, 6 and 8-11.

[0208] A modification of the instant cheek airway is designed to enable incorporation of a mouth-corner retainer element in a single, in-line manufacturing process by simply extending the length of the hollow tube with flexible joints inserted to enable the tube to fold about the corner of a user's mouth and along the outer wall of a user's cheek, depicted as element 22 in Figures 4, 10 and 11. The tube can even be manufactured in-line with sufficient length to curve about a user's ears, as element 25 in Figures 10 and 11. Adaptation of the hollow tube for in-line manufacturing is preferred to eliminate the necessity to add flanges by some additional assembly process, and has the added features of easier packing, shipping and display, while enabling the end user to fold the in-line tube for better personal fit.

[0209] Tongue-Avoiding Feature. In one preferred modification of the cheek airway invention, at least one of the rear-tooth corner portion 4, the rear-jaw gap portion 5 and the tongue portion 6 of the airway is stiffly flexible so that a user's tongue can press the airway into locations of lesser interference with the user's tongue, near the side and roof of the user's rear-mouth cavity. Not only does the resulting configuration reduce interference with the user's tongue, but also it can help retain the airway in the user's cheek pathway.

[0210] Tube Diameters Related to Rear-jaw Gap and Lip Seal. By comparison to the 2 to 3 mm inside diameter which is explicitly disclosed for the pressure-equalization conduit of Pope, et al., U.S. Patent 4,553,549, larger diameters are preferred for the instant invention, to the extent that the user's rear-jaw gap can accept such larger diameters; larger diameters enable the higher flow volumes desired for the breath-supplementation function of the instant invention. By way of non-limiting example, tube inside diameters of approximately 5.5 mm to 6.5 mm, have been used in the instant

invention for an adult human. The instant invention is not specifically limited to such range of diameters, but rather it typically will be limited by the cross-sectional area of the particular user's rear-jaw gap.

[0211] Lip-sealing problems can be mitigated in the instant invention by employing a smaller diameter tube around which a user's lips still can nearly seal. When using such smaller diameter tubes, one accepts that the resulting lesser air flow through the cheek path airway may only supplement, not entirely replace, nasal breathing. However, lip sealing tends to be a less critical issue in the instant invention because the invention is founded in part upon a recognition that there can be benefit to preservation of some nasal air flow by using a cheek path airway merely to supplement nasal air flow rather than replacing it; as a result a tube smaller than the diameter tube required to completely replace nasal breathing can be employed to more readily allow the user's lips to seal about the tube.

[0212] In many instances the maximum radial cross-section of a tube which can be fitted to a user's rear-jaw gap also will be small enough to allow the a user's lips to seal around the instant cheek airway tube sufficiently to render lip sealing an insignificant issue. While it is desirable in the instant invention to preserve a user's normal lip seal when the user is breathing nasally, the instant invention is designed to not prevent and not hinder open-mouth breathing when the user's physiologic state naturally triggers a switch from nasal to open-mouth breathing. When supplementing nasal air flow, the instant invention does not necessarily require a strict lip seal, but it is desirable to enable a user to substantially preserve the user's natural lip seal.

[0213] Methods of Making and Using.

[0214] The cheek path airway can be manufactured from plastic materials such as those in use for flexible drinking straws, provided that they be essentially non-toxic. It is conceived that the cheek path airway could be manufactured by modification of methods and machines presently widely used for the manufacture of flexible drinking straws.

[0215] Portions of a relatively rigid tube can be rendered flexible by imposing corrugations in the tube wall similar to those which render plastic drinking straws flexible. Such corrugations can render a tube somewhat extensible as well as flexible. A wide variety of methods could impart the essential curves to fit a user's cheek path.

1 For example, portions of the tube could be rendered flexible by helical coils of wire or
2 filament covered by an outer sheath; or semi-rigid, simi-flexible tubing could be used
3 throughout and adjusted by hand molding to fit a cheek pathway. Materials of differing
4 flexibility could be fused or welded together. The degree of flexibility versus rigidity
5 could be altered by controlling the thickness of the tube walls and their chemical
6 composition.

7 [0216] The thickness of the walls of plastic tubes can be adjusted to enable such tube
8 walls to deform to a flattened or oval shape, which better conforms to the cross-section
9 of a particular user's rear-jaw gap, but without collapse of the hollow air passageway.
10 The deformation can be flexible or malleable, as well as resilient. For comfortable fit, it
11 is preferable that the outer surface of the rear-jaw gap portion 5 of the airway tube be
12 smooth, rather than corrugated, to minimize irritation when the jaws close the rear-jaw
13 gap to its minimum cross-section.

14 [0217] Airflow openings and filament-lacing holes can be melted through the walls of
15 plastic tubes by use of a heated pointed instrument. It is conceived that the tube walls
16 could be initially formed with such openings, or openings could be cut or stamped, or
17 formed with a focused laser beam.

18 [0218] It is conceived that in a combination of the cheek pouch anchor with the cheek
19 path airway, much of the stabilizing function can be assumed by the anchor, permitting
20 a wider range in the design of flexibility and rigidity in the tube.

21 [0219] The filament used in the cheek pouch anchor can be manufactured from
22 monofilament plastic line similar to that in common use for heavier weights of fishing
23 line, provided that it be essentially non-toxic. Flexibility and resilience can be controlled
24 by controlling the size of the cross-section of the monofilament, as well as its
25 composition. It is conceived that flexibility and resilience also could be affected by
26 changes in the shape of the monofilament's cross-section. Such monofilament line can
27 be heat-molded at relatively low temperatures into curves of the desired shapes and it
28 develops a "memory" for such a heat-molded shape which aids shaping of spring-like
29 curves in the monofilament line. Altering the locations of the lacing holes 17 in portion
30 3 of the airway tube alters the shape of the curves in the cheek pocket anchor. The
31 filament could be formed of metal or a combination of metal and plastic.

32 [0220] The cheek path airway, the cheek pouch anchor, and the combination of them,

can be sanitized in an ordinary household dishwasher in the same manner as dining utensils, provided that temperatures in the machine are not so high as to excessively soften the materials of the devices.

[0221] Because all parts can be formed of plastic, it is conceived that the cheek path airway, and possibly the combination of the cheek path airway and cheek pouch anchor, could be manufactured and assembled sufficiently inexpensively for short term use and possibly to be disposable.

[0222] Some Definitions Used in the Claims.

[0223] For purposes of the claims the following words have the following meanings:

[0224] "Conduit" means a hollow tube or channel capable of conveying fluids along its longitudinal axis, which axis may be curved. A conduit may have one or more separate passageways through it and thus have a plurality of longitudinal axial dimensions. The conduit's cross-section may enclosed (as in a tube by way of non-limiting example), or partially open (as in an open-top channel by way of non-limiting example). The conduit's radial cross-section may have a single-focus radius (circular cross-section) or may have multi-focal radii or variable length radii and thus have a plurality of radial dimensions (oval or other variant shape which can include multi-lateral shapes, that is, a plurality of sides). A conduit's radial cross-section may vary along the conduit's longitudinal axis.

[0225] "Curve" means a geometric figure which may have any degree of curvature; it may but need not include zero curvature, that is, a straight line, as well as positive or negative curvature.

[0226] "Filament" includes at least one thread, fibre, strand, wire, line, string, strip, or the like. It may include multi-strand or braided configurations. The radial cross-section of the filament may, but need not necessarily be, circular.

[0227] "Flexible" includes bendable, pliable, moldable, and adjustable.

[0228] "Portion" of a conduit refers to an approximate functional location or position along the longitudinal axis of the conduit, without necessarily implying sharp or distinct boundaries between portions and functions; one portion may have an indistinct or blended joinder with another

- 1 portion, and when the conduit is installed in a user's mouth a portion may
- 2 conform only approximately to the indicated parts of a user's mouth.

CLAIMS

I claim:

Claims 1 - 32 (withdrawn from prosecution per restriction requirement).

Claim 33 (original): A cheek pouch anchor,
for placement within a user's cheek pouch to maintain positioning of a work piece in a
user's mouth while a user's jaws, inter occlusal space, and lips open and close,
comprising:

A spring element adapted
- to be placed within a user's cheek pouch, and
- to compress as a user's jaws close, and
- to resiliently expand so as to form and maintain a span bridging across a user's
inter occlusal space and a user's lip opening formed as a user's jaws and lips
open and close, and
- to receive joiner to a work piece, and
having structural strength sufficient, when joined to a work piece, to maintain placement
within a user's cheek pouch while a user's lips and jaws open and close.

Claim 34 (original): The cheek pouch anchor of claim 33 wherein said spring element
is formed of at least one of the following:

metal,
plastic,
resilient monofilament plastic line.

Claim 35 (original): The cheek pouch anchor of claim 33 further comprising:
said cheek pouch anchor is joined with a conduit for a fluid, which conduit is
adapted for placement at least partially in a user's cheek pouch.

1 Claim 36 (original): The cheek pouch anchor of claim 33 wherein said spring element
2 comprises:
3 a resilient filament
4 - which is configured into a plurality of connected loops, each loop having
5 a loop span size, and
6 -said plurality of loops are combined to form a whole spring element with
7 a whole spring element span size, and
8 - each one of said plurality of loop span sizes is mutually adjustable
9 relative to at least one other of said loop span sizes, such that an increase or decrease
10 in the loop span size of any one of said plurality of loops results in a converse decrease
11 or increase in the loop span size of at least one other of said plurality of loops,
12 thereby enabling adjustment of said whole spring element span size by said mutual
13 adjustment within said plurality of loop span sizes.
14
15 Claim 37 (original): The cheek pouch anchor of claim 33, improved to dispense a
16 substance within a user's mouth, wherein said spring element is adapted to receive
17 impregnation or coating with a substance which is to be released in a user's mouth.

1 Claim 38 (Added by Preliminary Amendment): A cheek pouch anchor, for placement
2 within a user's cheek pouch, comprising:
3 A spring element adapted
4 - to be placed within a user's cheek pouch, and
5 - to compress as a user's jaws close, and
6 - to resiliently expand so as to form and maintain a span
7 --- bridging across such user's inter occlusal space as such user's
8 jaws open, and
9 --- bridging across such user's lip opening formed as such user's
10 lips open, and
11 - to receive impregnation or coating with a substance which is to be
12 released within such user's mouth,
13 whereby said spring element is enabled to maintain its placement within a user's cheek
14 pouch and to release such substance while such user's lips and jaws remain free to
15 open and close.

1 Claim 39. (new) An adjustable cheek pouch anchor, for placement within a user's
2 cheek pouch to maintain positioning of a work piece in a user's mouth while a user's
3 jaws, inter occlusal space, and lips open and close, comprising:
4 a spring element formed of a resilient filament
5 sized to fit within a user's cheek pouch, and
6 having a dynamic span
7 that is resiliently expandable within a user's cheek pouch to maintain a
8 bridge across a user's inter occlusal space and lip opening that form as a
9 user's jaws open, and
10 that is flexibly compressible to allow a user's jaws and lips to fully close
11 while said spring element is within a user's cheek pouch, and
12 capable of receiving attachment of a work piece, and
13 having structural strength that is sufficient for said spring element to maintain
14 itself, with a work piece attached to it, within a user's cheek pouch while a user's
15 jaws open and close; and
16 said resilient filament
17 is configured into a plurality of connected loops
18 each such loop having a loop span size, and
19 each such loop span size having a range of expansion and compression,
20 and
21 said plurality of connected loops form a whole spring element having a whole
22 spring element span size, and
23 said whole spring element span size having a range of expansion and
24 compression, and
25 said range of expansion and compression of least one of said loop span
26 sizes of said plurality of connected loops is adjustable relative to at least
27 one other of said loop span sizes, and
28 said connected loops translate an adjustment in said range of expansion and
29 compression of the loop span size of at least one of said plurality of connected
30 loops into an adjustment in said range of expansion and compression of said
31 whole spring element span size.

1 Claim 40. (new) A cheek pouch anchor, for placement within a user's cheek pouch and
2 releasing a substance in a user's mouth, comprising:
3 A spring element
4 sized to fit within a user's cheek pouch, and
5 having a dynamic span
6 that is resiliently expandable within a user's cheek pouch to maintain a
7 bridge across a user's inter occlusal space and lip opening that form as a
8 user's jaws open, and
9 that is flexibly compressible to allow a user's jaws and lips to fully close
10 while said spring element is within a user's cheek pouch, and
11 having the capability to carry a substance, and
12 having structural strength that is sufficient for said spring element, while carrying
13 the substance, to maintain itself within a user's cheek pouch while a user's jaws
14 open and close, and
15 having the capability to release the some portion of the substance into the user's
16 mouth.
17

1 In response to the Office Action of February 21, 2007, the abstract is wholly replaced
2 as follows:

3 ABSTRACT

4 Delete the entire original abstract.

5 Replace the original abstract with the amended abstract on the following page:

ABSTRACT

The cheek pocket anchor, formed of a resilient filament, fits within a user's cheek pouch. The anchor dynamically spans a user's inter-occlusal space and lip opening as a user's jaws open and close. The anchor can be formed of inter-connected, adjustable loops to enable user adjustment of its whole span. It can stabilize a work piece, such as an airway, in a user's mouth. The cheek path airway fits a path between a user's lips and through the user's cheek pouch and rear-jaw gap, avoiding the user's bite. It provides supplemental air to a user's rear-mouth cavity independently of a user's nasal airways while a user's lips remain closed. It can be used in combination with mandibular jaw-control and tongue-control devices whereby the combination mitigates breathing restrictions in a user's nasal and throat airways. It can be manufactured in-line and folded by a user to fit the user's cheek pathway.

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Respectfully submitted

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Applicant